Atty. Dkt. No. 053466/0274

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Masayuki TSUCHIYA

title:

NATURAL HUMANIZED ANTIBODY

Appl. No.:

09/509,098

Filing Date:

March 22, 2000

Examiner:

Helms, L.

Art Unit:

1642

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents Washington, D.C. 20231

Sir:

This is in response to the Restriction Requirement mailed on March 5, 2001. A Petition for a three-month extension of time with the requisite fee, to extend the time to respond to July 5, 2001, is enclosed. Should such a request or any fee be deficient or absent, consider this paragraph such a request and authorization to charge the appropriate fee under 37 C.F.R. §§1.16 to 1.18 to Account No. 19-0741.

In response to the Restriction Requirement mailed on March 5, 2001, applicant hereby provisionally elects Group I, claims 1-5, drawn to a method for preparing a humanized antibody, with traverse. Applicant reserves the right to file divisional application(s) on non-elected subject matter.

The Examiner classified the claims into three groups: Group I is drawn to a method for preparing a humanized antibody; Group II is drawn to a natural humanized antibody and compositions comprising the same; and Group III is drawn to DNA, expression vectors, host cells and method of claims. The Examiner alleges that because the technical feature recited in claim 1 is not special, the groups are not so linked as to form a single general concept under PCT Rule 13.1. Applicant respectfully traverses this restriction.

Especially, with respect to the restriction between Groups I and II, applicant notes that Group I is drawn to a process and Group II is drawn to a product obtained

by the claimed process. Inventions of groups I and II exhibit the requisite special technical features because the product of group II is produced by the process of group I. Therefore, there is a technical relationship between inventions of Groups I and II regardless of alleged lack of novelty.

As to the restriction requirement between Groups II and III, applicants direct the Examiner's attention to Example 17, Part II, Annex B of the Administrative Instructions Under the PCT (see page AI-43 of the MPEP). Example 17 describes two claims, one reciting a protein X, and the other reciting a DNA sequence encoding protein X. There is unity of invention between these two claims because "[e]xpression of the DNA sequence in a host results in the production of a protein which is determined by the DNA sequence. The protein and the DNA sequence exhibit corresponding special technical features" (emphasis added). This is identical to the inventions between Groups II and III, thus there is also unity of invention between these two groups.

For the reasons indicated above, both restriction requirements are improper and should be withdrawn. Applicants earnestly await receipt of the initial Office Action on the merits.

Respectfully submitted,

Date July 5, 2001

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AMENDMENT IN RESPONSE TO NOTICE UNDER §§1.821-825

Commissioner for Patents Washington, D.C. 20231 BOX SEQUENCE

Sir:

In response to the Notice to Comply with Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures, mailed March 5, 2001, please amend the application as follows:

## **IN THE SPECIFICATION:**

On page 61, delete Table 3, and replace this with the following in accordance with 37 C.F.R. § 1.121. A marked up version showing changes is attached:

## Table 3

## The amino acid sequence of the L chain V region



						FRI					CDRI		E	R2	
							1		2		3			4	
						12345678	8901234	56789	0123	456	78901	234	56789	01234	56789
AΗ	M	(SEQ	ΙD	NO:	130)	DIVMTQSI	HKFMSTS	VGDRV	SITC	KAS	QDVNT.	AVA	WYQQF	KPGQSP	KLLIY
Hu	SG	I(SEQ	ID	NO:	131)	DIQMTQS	PSSLSAS	VGDRV	TITC				WYQQF	KPGKAP	KLLIY
RE	I	(SEQ	ΙD	NO:	132)	DIQMTQS	PSSLSAS	VGDRV	TITC				WYQQF	KPGKAP	KLLIY
RV	La	(SEQ	ΙD	NO:	133)										
RV	Lb	(SEO	ID	NO:	134)		<b></b>								